AffloVest® Instructions for Use and User Manual

Frees patients. Mobilizes secretions. Advances therapy.

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 10,000s of people just like you. To ensure that you derive maximum benefit from the AffloVest and to ensure your safety, please familiarize yourself with the information in this AffloVest User Manual.

The AffloVest User Manual contains important SAFETY and TECHNICAL DATA. Please keep this manual in a safe place for easy reference.

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

Table of Contents

Explanation of Symbols

SYMBOL	EXPLANATION	SYMBOL	EXPLANATION	SYMBOL	EXPLANATION
	Caution		Standby		Refer to Instructions for Use
	Type BF Equipment - All parts considered applied parts		Play/Pause		Keep dry
	Direct Current		High Intensity		Do not tumble dry
	Manufacturer		Medium Intensity		Do not iron
REF	Reference Number		Low Intensity		Do not wet clean
LOT	Lot Number		Do not machine wash		Do not bleach
SN	Serial Number		Waste electrical and electronic equipment; do not dispose in household waste. Dispose of equipment in accordance with all relevant local, state and federal regulations.	IP42	Protected against ingress of solid foreign objects ≥0.04" (1.0 mm) in diameter and dripping water (at 15° tilt).

Technical Data

Nominal voltage:	14.4VDC – 14.8VDC
Nominal power consumption:	Approx. 30W
Power supply:	Battery operated AC/DC power. Please see directions for use that come with power supply. The provided power supply is specified as part of the AffloVest system.
Lithium-ion battery:	MODEL: 8052 OUTPUT: 14.4VDC – 14.8VDC, 5.2Ah typ – 6.2Ah typ, 77Wh – 89Wh, Li-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:	Seven sizes available: XXS (Extra Extra Small) XS (Extra Small) S (Small) M (Medium) L (Large) XL (Extra Large) XXL (Extra 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 maximum 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 shut-off.

User Information

⚠ **IMPORTANT**

The AffloVest should be worn over clothing or with a fabric shield to prevent cross-contamination in a clinic or hospital setting where more than one patient uses the unit. The AffloVest should be cleaned appropriately between patient use, see the Cleaning the AffloVest section.

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

Indications for Use/Method/ Application

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.

Method

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
- 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.

Unpacking and Using the AffloVest for the First Time

⚠ **IMPORTANT**

Please follow the steps in order to ensure proper set-up. Battery must be fully charged before use (this is covered in the steps below).

Step 1: Unpacking the AffloVest

Carefully unpack the AffloVest and its accessories.

Package contents:

AffloVest

Rechargeable Battery (Li-ion)

Power Supply

Carrying Case

User Manual

Step 2: Checking Battery Level and Charging Battery

⚠ IMPORTANT

Use only the supplied rechargeable battery and the supplied power supply to ensure safe and reliable operation of the AffloVest.

To check the battery level, depress the fuel gauge push-button to activate the fuel gauge LEDs.

Battery level push button

The battery LEDs will light up to indicate the battery level:

1 LED blinking	2 LEDs lit	3 LEDs lit	4 LEDs lit	5 LEDs lit
0 –19%	20–39%	40–59%	60–79%	80–100%

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.

Power Supply LED lit

Next, plug the power supply plug into the AffloVest battery. There is a small opening at the bottom of the battery pouch.

Power supply connected to battery

⚠ IMPORTANT

- When the power supply is plugged into the battery, pay close attention not to place any strain onto 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 (1) 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 (3) hours and until all LEDs are solidly lit. At the completion of charging, 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 gauge LEDs will remain lit for approximately one (1) minute after removing the power supply.

Step 3: 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. The serial number tag is included inside the battery pouch.

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 re-connecting the AffloVest battery, the controller should beep 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!

⚠ **IMPORTANT**

- 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.

Fitting the AffloVest

- Unbuckle the chest buckles on the AffloVest and set the buckles to maximum size.
- Put on the AffloVest and fasten all 3 buckles. Firmly pull the buckle straps so that the vest fits snugly on the body, but does not restrict a deep, full breath. After adjusting, the sides of the AffloVest should have less than a 5 inch (12.7 cm) gap. They may overlap up to 1 inch (2.5 cm).
- Adjust the shoulder snaps to place the front upper AffloVest motors on the upper chest just below the collar bone.

Controller Layout

(Standby)	Press and hold to turn controller On and Off
GO	Press to start pre-programmed **GO** sequences
P **V** **D**	Percussion, Vibration, Drainage modes
	High intensity
	Medium intensity
	Low intensity
(Play/Pause)	Press to start treatment from Main Menu. Press to select Program/ Usage Menus
(Up/Down)	Press to navigate through menu items
(Left/Right)	Press to change current highlighted selection

Running a Treatment Cycle

When the AffloVest is properly setup, press and hold the (Standby) button on the controller. After a brief start-up period (Figure 1), the controller will navigate to the Main Menu (Figure 2).

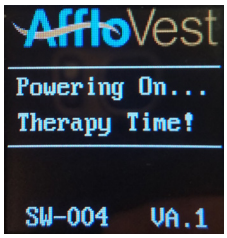

Figure 1. Welcome Screen

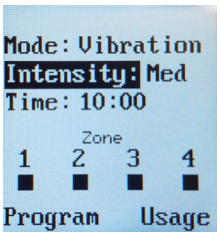

Figure 2. Main Menu

Treatment may be started at any time by hitting the (Play/Pause) button from the Main Menu. Pressing the following buttons will update the treatment whether the vest is running or not:

- **P:** Percussion mode, all motors operate in a pulsed fashion.
- **V:** Vibration mode, all motors operate continuously.
- **D:** Drainage mode, motors operate in a pre-programmed sequential fashion.
- **GO:** Automatically starts the **GO** mode, the system will perform the following treatments sequentially (by default):
  - Percussion mode, 10 minutes duration at Medium intensity (followed by a 10 second pause)
  - Vibration mode, 10 minutes duration at Medium intensity (followed by a 10 second pause)
  - Drainage mode, 10 minutes duration at Medium intensity

The AffloVest will start in the Medium intensity mode by default. Pressing the following buttons will update the treatment whether the vest is running or not:

- High intensity
- Medium intensity
- Low Intensity

While treatment is running, the AffloVest may be paused by pressing the (Play/Pause) button. This shall suspend treatment until the (Play/Pause) button is pressed again.

While paused, press and hold the (Play/Pause) button to reset the treatment time to the previous setting.

Indicators

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

- **Zone Indicator**: Displays which motor zones are currently active during treatment.
- **Low Battery Indicator**: When the battery is low, a battery icon will flash alerting the user. The controller will also beep to alert the user to charge the battery.

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

- **Fuel Gauge:** Displays the battery level when the button is pressed.

Menu Navigation

Press the ^ (Up) and v (Down) buttons to navigate through menus on the controller. To change the value, press the < (Left) and > (Right) buttons while the value is highlighted.

To navigate to the Program Menu or Usage Menu, navigate to the desired menu selection. Press the ▶II (Play/Pause) button to navigate to that menu.

Program Menu

Navigating to the Program Menu (Figure 3) allows the user to modify the default **GO** treatment settings.

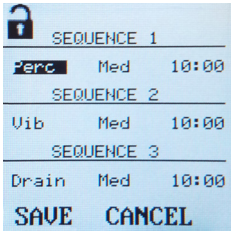

Figure 3. Program Menu

Modify the settings as desired within the following allowable ranges:

- Treatment Type: Percussion, Vibration, Drainage
- Treatment Time: 5–15 Minutes
- Treatment Intensity: Low, Medium, High

Select "Save" and press the ▶II (Play/Pause) button to save the settings. To exit without saving select "Cancel" and press the ▶II (Play/Pause) button.

The next time the **GO** button is pressed from the Main Menu the new treatment settings will be run.

Usage Menu

Navigating to the Usage Menu (Figure 4) allows the user to view run-time information.

Figure 4. Usage Menu with Run-Time Information

Press the ▶II (Play/Pause) button to return to the Main Menu.

Turning off the AffloVest

To turn off the AffloVest controller, press and hold the ⏻ (Standby) button for at least two (2) seconds. The system will enter a standby mode.

Alternatively, to turn off the AffloVest controller, remove the power by disconnecting the battery cable from the vest plug.

Transportation, Operation and Storage Conditions

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

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 700–1060 hPa.

Traveling with Lithium-ion Batteries

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

Cleaning the AffloVest

Clean the AffloVest in the following situations:

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

To clean the AffloVest, please 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. Using 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 front buckles and shoulder snaps 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 snaps and straps.
   c. Wipe inside and outside of buckle and buckle connector.
   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).

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, please 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.

Cleaning and Care Warnings

⚠ **IMPORTANT**

	Do not machine wash
	Do not bleach
	Do not tumble dry
	Do not iron
	Do not wet clean

Battery Warning Information

⚠ **IMPORTANT**

- 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 non-combustible, heat resistant and non-conductive surface.

Safety Information: 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 handhold 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.

Safety Information: 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 and 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 he 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

Electrical and electronic products must be disposed of separately from any household waste at the end of their service. To ensure that these products are recycled effectively, deposit them at municipal collection points for recyclable materials where they will be accepted free of charge.

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.

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 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 dealer 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	Start a new therapy cycle. Ensure battery if fully charged, attempt to operate when connected to power supply. Contact your dealer 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 dealer for further assistance.

Resetting the AffloVest

Step 1: Verify the Battery Is Fully Charged

Press the button on the battery.

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

Step 2: Disconnect the Battery From the AffloVest

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

Open battery compartment and disconnect battery as shown, leave disconnected sixty (60) seconds

Plug battery back in, controller should beep twice when plugged back in to battery

Step 3: Attempt To Run the AffloVest

Press and hold the ⏻ (Standby) button for 3–5 seconds until the screen turns on:

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	

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.

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.

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.

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 broadcast and TV broadcast 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 re-orienting 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.

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[3] is warranted to be free from defects in material and workmanship for a period of five (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 one (1) year from the date of shipment.

For "Non U.S." original purchasers[2], the AffloVest, and controller are warranted to be free from defects in material and workmanship for a period of five (5) years from the date of shipment. The battery[3] and "Go Anywhere" case is warranted to be free from defects in material and workmanship for period of one (1) year from the date of shipment.

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 user 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 Manual, 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 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.

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

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 where purchaser can be reached.
d. Proof of purchase.

3. Ship the item, postage pre paid.

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 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.

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. "Non-U.S. Purchasers" are all other Purchasers. A warranty period measured in years begins on the date of original purchase.
3. Batteries shall not be deemed defective unless the battery capacity is less than 50% of its original rated capacity.